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**PATENT APPLICATION**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re application of

Docket No: Q97391

Akio SUGIHARA, et al.

Appln. No.: 10/594,127

Group Art Unit: 1636

Confirmation No.: 8975

Examiner: Not yet assigned

Filed: September 25, 2006

For: COMPOSITION OF SOLIFENACIN OR SALT THEREOF FOR USE IN SOLID FORMULATION

**INFORMATION DISCLOSURE STATEMENT**  
**UNDER 37 C.F.R. §§ 1.97 and 1.98**

**MAIL STOP AMENDMENT**

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

Sir:

In accordance with the duty of disclosure under 37 C.F.R. § 1.56, Applicant hereby notifies the U.S. Patent and Trademark Office of the documents which are listed on the attached PTO/SB/08 A & B (modified) form and/or listed herein and which the Examiner may deem material to patentability of the claims of the above-identified application.

One copy of each of the listed documents is submitted herewith, except for the following: U.S. patents and/or U.S. patent publications; and co-pending non-provisional U.S. applications filed after June 30, 2003.

The present Information Disclosure Statement is being filed: (1) No later than three months from the application's filing date; (2) Before the mailing date of the first Office Action on the merits (whichever is later); or (3) Before the mailing date of the first Office Action after

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U.S. Appln. No.: 10/594,127

filings a request for continued examination (RCE) under §1.114, and therefore, no Statement under 37 C.F.R. § 1.97(e) or fee under 37 C.F.R. § 1.17(p) is required.

In compliance with the concise explanation requirement under 37 C.F.R. § 1.98(a)(3) for foreign language documents, Applicant submits the following explanations:

WO 96/20194 A1:

The above document corresponds to U.S. Patent 6,017,927.

WO 03/103659 A1:

The above document corresponds to U.S. Publication 2006/0035923 A1.

JP-A-2003-261439:

An English abstract and translation are attached.

JP-A-9-71764:

An English abstract and translation are attached.

JP-A-9-110698:

An English abstract and translation are attached.

JP-A-10-7547:

An English abstract and translation are attached.

JP-A-5-194218:

The above document corresponds to U.S. Patent 5,534,534.

JP-A-62-136240:

The above document corresponds to U.S. Patent 4,870,059.

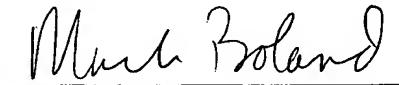
The submission of the listed documents is not intended as an admission that any such document constitutes prior art against the claims of the present application. Applicant does not

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U.S. Appln. No.: 10/594,127

waive any right to take any action that would be appropriate to antedate or otherwise remove any listed document as a competent reference against the claims of the present application.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,



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CUSTOMER NUMBER

Date: January 25, 2007



Substitute for Form 1449 A &amp; B/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet

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of

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Complete if Known	
Application Number	10/594,127
Confirmation Number	8975
Filing Date	September 25, 2006
First Named Inventor	Akio SUGIHARA
Art Unit	1636
Examiner Name	Not yet assigned
Attorney Docket Number	Q97391

**U.S. PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Document Number		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document
		Number	Kind Code <sup>2</sup> (if known)		
		US 6,017,927	A	01/25/2000	Takeuchi et al.
		US 2006/0035923	A1	02/16/2006	Van Meeteren et al.
		US 4,870,059		09/26/1989	Mitsuhashi et al.
		US 5,534,534	A	07/09/1996	Makino et al.

**FOREIGN PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document			Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Translation <sup>6</sup>
		Country Code <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)			
		WO	96/20194	A1	07/04/1996		English abstract
		WO	03/103659	A1	12/18/2003		English abstract
		JP	2003-261439	A	09/16/2003		English translation
		JP	9-71764	A	03/18/1997		English translation
		JP	9-110698	A	04/28/1997		English translation
		JP	10-7547	A	01/13/1998		English translation
		JP	5-194218	A	08/03/1993		No
		JP	62-136240	A	06/19/1987		No

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city, and/or country where published.	Translation <sup>6</sup>
		Yasushi et al., "Effects of Compression Pressure on Physical and Chemical Stability of Tablets Containing an Anticancer Drug TAT-59(-3)" (1994), Chem. Pharm. Bull., Vol. 42, No. 12, pp. 2582-2587	English
		Owen C. Chidavaenzi et al., "The effect of co-spray drying with polyethylene glycol 4000 on the crystallinity and physical form of lactose" (2001), International Journal of Pharmaceutics, Vol. 216, pp. 43-49	English
		Ching-Wei et al., "Effect of particle size on the available surface area of nifedipine from nifedipine-polyethylene glycol 6000 solid dispersions" (1996), International Journal of Pharmaceutics, Vol. 127, pp. 261-272	English
		Deirdre O. Corrigan et al., "The effect of spray drying solutions of bendroflumethiazide/polyethylene glycol on the physicochemical properties of the resultant materials" (2003), International Journal of Pharmaceutics, Vol. 262, pp. 125-137	English
		Claes Ahlneck et al., "The molecular basis of moisture effects on the physical and chemical stability of drugs in the solid state" (1990), International Journal of Pharmaceutics, Vol. 62, pp. 87-95	English

Examiner Signature	Date Considered

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>See Kind Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov). MPEP 901.04 or follow the hyperlink from the title of the document to the intranet. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST. 3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup>Applicant is to indicate here if English language Translation is attached.